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|---|---------------|----------------------|-----------------------|------------------|
| APPLICATION NO.   | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
| 10/593,808  | 09/20/2006    | Craig A. Coburn      | 21664YP               | 4626             |
| 210   | 7590          | 10/01/2009           | EXAMINER              |                  |
| MERCK AND CO., INC<br>P O BOX 2000<br>RAHWAY, NJ 07065-0907 |               |                      | STOCKTON, LAURA LYNNE |                  |
| ART UNIT  | PAPER NUMBER  |                      |                       |                  |
|   |               | 1626                 |                       |                  |
| MAIL DATE   | DELIVERY MODE |                      |                       |                  |
| 10/01/2009  | PAPER         |                      |                       |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |
|------------------------------|--------------------------------------|--------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/593,808 | <b>Applicant(s)</b><br>COBURN ET AL. |
|                              | <b>Examiner</b><br>Laura L. Stockton | <b>Art Unit</b><br>1626              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on September 20, 2006 {Prelim. Amendment}.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-23 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Claims 1-23 are pending in the application.

***Election/Restrictions***

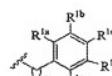
Restriction is required under 35 U.S.C. 121 and 372.

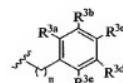
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g.  $R^1$ ,  $R^2$ ,  $R^4$ , etc., and their widely divergent meanings, a precise listing of inventive groups cannot be made.

The following groups are exemplary:

**Group I.** Claims 1-7 and 17-19 (in-part), drawn to

products of formula (I) wherein  $R^1$  is  ,  $R^2$  is

$R^3$  is  , and  $R^4$  is hydrogen or C<sub>1-6</sub>alkyl, and  $R^4$  is hydrogen or C<sub>1-6</sub>alkyl.

**Group II.** Claims 1, 4, 5, 8-13 and 17-19 (in-part),

drawn to products of formula (I) wherein  $\mathbf{R}^1$  is

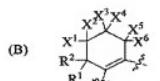
$\mathbf{R}^2$  and  $\mathbf{R}^3$  are linked to form a carbocyclic ring (A),



(A) and  $\mathbf{R}^4$  is hydrogen or  $C_{1-6}$ alkyl.

**Group III.** Claims 1, 14, 15 and 17-19 (in-part),

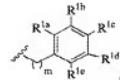
drawn to products of formula (I) wherein  $\mathbf{R}^1$  is hydrogen (see claim 15) or  $C_{1-6}$ alkyl,  $\mathbf{R}^2$  is hydrogen or  $C_{1-6}$ alkyl, and  $\mathbf{R}^3$  and  $\mathbf{R}^4$  are joined together to form a 6-membered



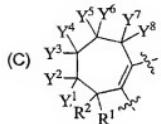
carbocyclic ring (B), .

**Group IV.** Claims 1, 4, 5, 16 and 17-19 (in-part),

drawn to products of formula (I) wherein  $\mathbf{R}^1$  is



**R<sup>2</sup>** is hydrogen or C<sub>1-6</sub>alkyl, and **R<sup>3</sup>** and **R<sup>4</sup>** are joined together to form a 7-membered carbocyclic ring (C),

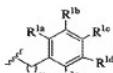
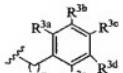


**Group V.** Claim 20 (in-part), drawn to a method of treating Alzheimer's disease by administering products

of formula (I) wherein **R<sup>1</sup>** is , **R<sup>2</sup>** is hydrogen or

C<sub>1-6</sub>alkyl, **R<sup>3</sup>** is , and **R<sup>4</sup>** is hydrogen or C<sub>1-6</sub>alkyl.

**Group VI.** Claim 21-23 (in-part), drawn to a method of inhibiting HIV protease, treating infection by HIV or treating AIDS by administering products of

formula (I) wherein  $\mathbf{R}^1$  is .  $\mathbf{R}^2$  is hydrogen or  $C_1$ -alkyl,  $\mathbf{R}^3$  is 

, and  $\mathbf{R}^4$  is hydrogen or  $C_{1-6}$ alkyl.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Again, this list is not exhausted as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and the examiner will endeavor to group the same.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a 2-amino-thiazole core, which does not define a contribution over the prior art. See, for example, the compound of CA Registry Number 4775-71-7 {Asinger et al., CA 64:27481, 1966}. The substituents on the core structure vary extensively and when taken as a whole result in vastly different compounds.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Additionally, the vastness of the claimed subject matter and the complications in understanding the

claimed subject matter imposes a burden on any examination of the claimed subject matter.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and

examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be

directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/  
Laura L. Stockton  
Primary Examiner, Art Unit 1626  
Group 1620  
Technology Center 1600

October 1, 2009